UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,351	03/29/2004	Gary Durack	INGURAN-PULSE	2698

28424 7590 07/23/2009

SANTANGELO LAW OFFICES, P. C.
125 SOUTH HOWES STREET
THIRD FLOOR
FORT COLLINS, CO 80521

EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
07/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,351	DURACK ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45,47-49,51-64 and 81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45,47-49,51-64 and 81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/9/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 45, 47-49, 51-64 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Potts et al (US 2003/0078703, submitted in the Information Disclosure Statement filed on December 17, 2007) in view of Shapiro et al (article from Cytometry, vol. 4, 1983, pages 11-19, submitted in the IDS filed December 17, 2007) and Piper et al (WO 92/08120).

Potts et al teach of a multi-channel cytometry analysis system that comprises a plurality of cytometry instruments 14a-14n adapted to operate in parallel. Any number of cytometry instruments 14 can be included in the system, and all are connected to an integrated platform comprising a common processor in the form of a database server 12. The database server 12 is in communication with a database 16. See Figure 1 in Potts et al. Potts et al teach that each of the cytometry instruments 14 can be a conventional apparatus such as a flow cytometer, a

fluorescence-activated cell sorter or a laser scanning cytometer. Raw data collected by the cytometry instruments 14 such as detected scattered light and fluorescence is received by the common processor or database server 12 substantially continuously, and the server 12 processes the output signals from the instruments 14. For example, the light intensity values measured for a single cellular event in each of the cytometry instruments 14 is transferred to the integrated platform of the database server 12, along with experimental data concerning operating parameters of the cytometry instruments. The database server 12 performs computations with the light intensity values and the experimental data. See Figure 1 and paragraphs 0021-0022, 0025 and 0026 of Potts et al. Potts et al fail to teach that the integrated platform containing the multiple flow cytometry units 14 has a common source of pulsed electromagnetic radiation that serves to provide a light radiation beam to each cytometry unit.

Shapiro et al teach of a multistation, multiparameter flow cytometer for analyzing and sorting mixed cell populations. In one embodiment, Shapiro et al teach of the use of a single beam from an ion laser as a source for illuminating several flow cytometers. A beam splitter is used to produce two or more beams from an incoming beam, and the split beams are used to illuminate stained cells in more than one flow cytometer. Shapiro et al teach that the flow chambers of the cytometers can be of the droplet-generation type. In addition, Shapiro et al teach that electronics for multiparameter signal processing such as computers can be used to evaluate the data measured on each of the cytometers. See the abstract, and pages 16 and 19 in Shapiro et al. Shapiro et al fail to teach that the laser which provides the single light beam that is split into multiple beams for illuminating stained cells in more than one flow cytometer is a pulsed laser.

Piper et al teach of a flow cytometer having a pulsed laser source for illuminating a stream of cells. A method of flow cytometry taught by Piper et al comprises the steps of producing a single file of cells through a region of a flow cytometer, shining a pulsed laser beam of pulse repetition frequency and diameter onto the region, collecting scattered and fluorescent light emitted by the cells in the region, and analyzing the collected light with a pulse height analyzer. Piper et al teach that the advantages of using a pulsed laser in a flow cytometry system include reliability, low power requirements, compact size, low cost, high instantaneous illumination intensities that give high signal levels, relaxed beam focusing requirements, good beam uniformity and wavelength versatility. Piper et al also teach that the light beam from a pulsed laser in a flow cytometry system can be split with a beam splitter. See the abstract and pages 2-3 and 7 of Piper et al.

Based upon the combination of Potts et al, Shapiro et al and Piper et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use a common source of pulsed electromagnetic radiation for providing an illumination light beam to each of the multiple flow cytometry units taught in the apparatus of Potts et al. since Shapiro et al teach that the provision of a common source of electromagnetic radiation to several flow cytometers is known and provides the advantage of using only a single source of light energy to illuminate multiple flow streams of particles, thus allowing multiple flow cytometers to be operated in parallel with less output of energy and less instrumentation, and Piper et al teach of the multiple advantages of using a pulsed laser beam in a flow cytometry system including better reliability, low power requirements, compact size, low cost, high instantaneous illumination intensities that give high signal levels, relaxed beam focusing requirements, good beam

uniformity and wavelength versatility. All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. With regards to instant claim 48, it would have been obvious to one of ordinary skill in the art to analyze sperm cells with the apparatus containing multiple flow cytometry units taught by Potts et al since it is well known in the prior art to analyze and sort sperm cells with a flow cytometer. With regards to claim 54, it would have been obvious to one of ordinary skill in the art to use flow cytometry units in the apparatus taught by Potts et al that contain an epi-illumination optics system since Potts et al teach that the cytometry units can be any type of conventional cytometry apparatus, and epi-illumination optics systems are routinely used in known, commercially available flow cytometers. With regards to claims 60-61, it would have been obvious to one of ordinary skill in the art to use jet-in-air droplet flow cytometry units in the apparatus taught by Potts et al since Potts et al teach that the cytometry units can be any type of conventional cytometry apparatus such as fluorescence-activated cell sorters, and these are routinely jet-in-air droplet flow cytometers.

With regards to claims 53, 56-58, 62, 64 and 81, Potts et al also fail to teach that the plurality of cytometry instruments are interchangeable modules in the common housing of the analysis system, and fail to teach that the processor or database server 12 is operable to output the rate at which particles are separated in the cytometry instruments, the decision boundary used by each instrument to discriminate between particles, and the operation of one instrument in relation to another instrument. However, it would have been obvious to one of ordinary skill in

the art at the time of the instant invention to render each of the cytometry instruments taught by Potts et al as an interchangeable module in the common housing of the analysis system so as to allow one of the instruments to be replaced when it is not working properly without having to replace or shut down the entire analysis system, thus allowing a more efficient operation of the system. It also would have been obvious to one of ordinary skill in the art to operate the processor or database server 12 taught by Potts et al to output the rate at which particles are separated in each cytometry instrument, the decision boundary used by each instrument to discriminate between particles, and the operation of one instrument in relation to another unit since these are common control parameters in a flow cytometer controlled by a processor such as a database server that provide an indication to an operator of the cytometer as to whether it is operating properly to sort particles and the criteria used to sort the particles.

4. Applicant's arguments filed April 9, 2009 have been fully considered but they are not persuasive.

Applicants argue the previous rejection of the claims made in the last Office action mailed on November 10, 2008 under 35 USC 103 as being obvious over Potts et al in view of Shapiro et al by stating that the claims now recite "a common source of pulsed electromagnetic radiation", and that neither Potts et al nor Shapiro et al teach of a shared, pulsed laser beam for multiple flow cytometry units for the classification of particles from a mixture of particles. In response to this argument and to the amendment made to the claims concerning a common source of pulsed electromagnetic radiation, the reference to Piper et al has been added to the rejection as evidence that the use of pulsed lasers or sources of electromagnetic radiation in flow cytometry systems is known and has many advantages over non-pulsed laser sources of

electromagnetic radiation. Based upon the combined teachings of Potts et al, Shapiro et al and Piper et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use a common source of pulsed electromagnetic radiation for providing an illumination light beam to each of the multiple flow cytometry units taught in the apparatus of Potts et al. since Shapiro et al teach that the provision of a common source of electromagnetic radiation to several flow cytometers is known and provides the advantage of using only a single source of light energy to illuminate multiple flow streams of particles, thus allowing multiple flow cytometers to be operated in parallel with less output of energy and less instrumentation, and Piper et al teach of the multiple advantages of using a pulsed laser beam in a flow cytometry system including better reliability, low power requirements, compact size, low cost, high instantaneous illumination intensities that give high signal levels, relaxed beam focusing requirements, good beam uniformity and wavelength versatility.

For the above reasons, Applicants' arguments and amendments are not found persuasive.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim, can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1797

mmw

July 20, 2009

/Maureen M. Wallenhorst/

Primary Examiner, Art Unit 1797